

K220834 Powder Free Nitrile Examination GloveJun 29, 2022
99 days to decisionK220834 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 22, 2022
Decision date	Jun 29, 2022
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Daxwell, LLC
Location	Houston, TX, US
Contact	Frank Zhang
510(k) history	2 submissions · 2 cleared · 2015-2022

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220834/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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